DESENSITIZING ANTI-TARTAR DENTIFRICE

This is a Continuation, of application Ser. No. 071,384, filed Jun. 4, 1993, now U.S. Pat. No. 5,352,439, issued Oct. 54, 1994, which is a continuation of application Ser. No. 778,532, filed Oct. 17, 1991 now U.S. Pat. No. 5,240,697, issued Aug. 31 1993.

This invention relates to desensitizing anti-tartar dentifrices and to a process for manufacturing them. More 10 particularly, it relates to such a dentifrice which includes a polyphosphate anti-tartar agent, such as tetrapotassium pyrophosphate, with a desensitizing agent which is a tooth pain inhibiting potassium salt, which is capable of passing through exposed dentin tubules to tooth nerves or neurons. 15 Such salts include potassium nitrate, potassium citrate, potassium oxalate and mixtures thereof.

Prior to the present invention it was known to utilize polyphosphates, such as pyrophosphates, as anti-tartar agents in oral compositions, including toothpastes and gels. 20 In U.S. Pat. No. 4,931,273 there are disclosed toothpastes containing tetrapotassium pyrophosphate as an anti-calculus (anti-tartar) agent. This patent and others teach that fluoride has been used in hardening the teeth and that polymeric polycarboxylates have been used as anti-calculus agents. 25 The patent also teaches that both fluoride and polymeric polycarboxylates help to prevent hydrolysis and enzymatic degradation of pyrophosphate.

U.S. Pat. No. 3,863,006 discloses that nitrates, such as potassium nitrate, when incorporated in aqueous solutions or 30 in toothpastes, desensitize the teeth during toothbrushing. Thus toothpastes that contain potassium nitrate desensitize the teeth and make them less painful or painless during brushing and flossing operations.

"Clinical Preventive Dentistry", Mason et al, Vol. 12, No. 35 6, January 1991, pages 6–12, titled "Evaluation of Tartar Control Dentifrices in In Vitro Models of Dentin Sensitivity" describes dentin sensitivity reduction with tartar control dentifrices containing PVM/MA copolymer (Gantrez S-97, GAF Corp.) as comparable to those obtained with commercial desensitizing dentifrices.

U.S. Pat. No. 4,992,258 to Mason describes a desensitizing dentifrice composition containing montmorillinite clay and, optionally, polycarboxylate copolymer such as Gantrez S-97 from GAF Corp.

Although both potassium pyrophosphate and potassium nitrate have been suggested as components of dentifrices, applicants' dentifrice and oral compositions, which contain both in one preparation, are believed to be novel, and their coaction to improve desensitization of the teeth and better 50 tartar control and inhibition is not suggested in any reference or combination of references of which applicants are aware.

In accordance with the present invention, a desensitizing, anti-tartar oral composition comprises an orally acceptable vehicle or base for such composition, an effective anti-tartar proportion of poly phosphate, and a desensitizing or tooth pain inhibiting proportion of a tooth pain inhibiting potassium salt which passes through exposed dentin tubules to tooth nerves and neurons. Among such tooth pain inhibiting compounds there may be mentioned various potassium salts, such as potassium nitrate, potassium citrate, potassium oxalate and mixtures thereof. Preferably, the polyphosphate is potassium pyrophosphate and the composition includes a potassium salt of a copolymer of maleic anhydride or maleic acid with vinyl methyl ether (SAPP, for synthetic anionic 65 polymeric polycarboxylate), potassium fluoride and potassium salt components, such as potassium lauryl sulfate and

2

potassium saccharin. However, providing that the total proportion of potassium in the composition is sufficient, in combination with the pain inhibiting compound, to improve pain inhibition, the sodium analogues of at least some of such compounds, such as tetrasodium pyrophosphate and disodium pyrophospate, may be present, at least in part. Also, anti-calculus phosphono compounds may be included in the invented oral compositions, including diphosphonic acids and phosphonoalkane carboxylic acid or their alkali metal salts, such as AHP (azacycloheptane- 2,2-diphosphonic acid), PPTA (phosphonopropane tricarboxylic acid), PBTA (phosphonobutane-1,2,4-tricarboxylic acid and EHDP (ethanehydroxy diphosphonic acid), each as acid or alkali metal salt, all preferably as potassium salts. It is applicants' theory that the presence of potassium ion in the present compositions aids in desensitizing the teeth in toothpastes and other oral compositions so that the teeth feel less pain than when brushed with control toothpastes that contain non-potassium polyphosphate with potassium nitrate or potassium citrate, and in which other components are nonpotassium compounds. In addition to the desensitizing effects of the invented compositions other beneficial results are obtained, due to the coaction of the components. Because tartar is removed and its recurrence is controlled, painful effects from its presence are diminished or eliminated and the pain-inhibiting potassium ions and any paininhibiting anions can better pass through any exposed dentin tubules to tooth nerves or neurons, which are thereby desensitized. It is recognized that removing tartar from the teeth may facilitate contact with underlying enamel or dentin of any pain provoking material, such as sugars, but it is considered that the desirable removal of tartar and the fact that it is an object to diminish pain experienced during toothbrushing (at which time the concentrations of desensitizing materials in the mouth and on the teeth are greatest and desensitization is therefore most effective) warrant employment of the invented compositions. Also, the invented compositions, when they contain a synthetic anionic polymeric poly-carboxylate (SAPP), such as potassium salt of a copolymer of maleic anhydride or maleic acid with vinvl methyl ether, appear to act to close off or narrow tubules in the dentin that could otherwise allow subsequent penetration to the pulp and neurons of pain causing materials, such as sugar solutions. That blockage of such tubules does not prevent passage of pain inhibiting ions to the neurons during toothbrushing because such ions are carried into the tubules with the copolymer and other components and also because they are smaller than sugar molecules and therefore can more easily pass through any restricted passageways or lattices. Another advantage of the invented compositions is that they reduce gum recession, which may in part be due to reduction in tartar deposition at the gum line and the absence of the irritation that it causes.

The principal components of the invented compositions are the polyphosphate and the desensitizing potassium compound, which is a salt. The desensitizing potassium salts utilizable in this invention include potassium nitrate, potassium citrate and potassium oxalate, with the first two being preferred. Mixtures including at least one of such salts are also useful, and in some circumstances they may also be mixed with other water soluble potassium salt(s), which are also capable of releasing potassium ions into the toothpaste and into the mouth and onto the teeth. However, care should be taken in choosing such other potassium salts to ensure that they do not cause the composition to taste objectionably salty or have any other undesirable flavor. It has been found that potassium nitrate and potassium citrate, in the propor-